



International Alliance for  
Biological Standardization

Montreal, Canada

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## 2<sup>nd</sup> IABS Real World Evidence Workshop : The Role of Alternative Approaches to Phase 3 Clinical Trials for Vaccine Efficacy and Licensure

*Human randomized controlled trials (RCTs) have long been the gold standard for evaluating the safety and efficacy of medicinal products, including vaccines. However, their resource-intensive and time-consuming nature may render them impractical and untimely, especially during health emergencies like the COVID-19 pandemic, where swift efficacy demonstration is crucial. As a result, there's increasing interest in exploring alternative approaches to generate fast evidence supporting efficacy prior to vaccine approval, complemented with collection of real world evidence in the post approval setting.*

*In a pre-approval setting, alternatives that have been discussed over the past year include inferring vaccine efficacy by assessing immune response markers elicited by a candidate vaccine, relying on correlates of protection (CoPs) or surrogate markers as well as controlled human infection models (CHIMs). These methods can under some condition provide reassurance of efficacy prior to approval, bypassing the need for demonstrating field efficacy using phase 3 RCTs. Indeed, while it's widely acknowledged that substituting phase 3 RCTs with alternative methods or a mix of them for vaccine licensure poses challenges, there might be specific situations where their application might not only be preferable, but potentially the only feasible and timely option. This strategy might be supplemented with a pre-agreed plan to verify effectiveness post-approval, including through use of real-world evidence.*

*IABS has a history of successfully organizing workshops on RWE, CHIMs and CoPs. In this upcoming meeting, we will bring together renowned vaccine experts from each of these varied disciplines. The objective of the meeting is to formulate recommendations and to initiate the creation of framework for the best use of various approaches to demonstrate vaccine benefit, not only an important requirement for vaccine licensing but also to confirm benefit in the post-approval setting.*

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